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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,218	04/15/2004	Paolo C. Trubiano	3085.ENC	1170

7590

04/24/2006

Karen G. Kaiser
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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,218	TRUBIANO ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1–21 are pending. Claims 1–17 are considered on the merits. Claims 18–21 are withdrawn from consideration as being drawn to a non-elected invention.

The elected species are β -glucoamylase and omega-3-fatty acids.

Claim Rejections – 35 USC § 103

Claims 1–17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,723,358 [B] in view of US 5,935,826 [C].

The claims are directed to a composition comprising an active agent encapsulated in a mixture comprising a soluble modified starch which has been derivatized to contain a hydrophobic group, and has been degraded by an exoenzyme, wherein the protein is a casein or a soy protein.

US 6,723,358 generically teaches a matrix composition that contains at least one encapsulated component (active agent) The agent may be an omega-3-fatty acid (col. 9, l. 20). The matrix is made by mixing at least one plasticizer such as oil or water and a particulate mixture which has at least one fat, one starch, one sugar. (abstract). Matrix starch materials may be modified or pregelatinized starches (col. 7, l. 37). A pregelatinized starch is a starch which has been gelatinized and then dried. The matrix may include gelatinized starches up to 30% by weight (col. 7, l. 27). The modified starch may be obtained by physical or chemical modifications to introduce hydrophobic properties (col. 8 l. 5). Soy protein or casein may also be included in the composition (col. 8, ls. 26–28). The encapsulated agent is protected against oxygen (col. 13, l. 45).

The reference lacks the specific disclosure of the modification of the starch by octenylsuccinic anhydride or dodecenylsuccinic anhydride.

US 5,935,826 disclose the instant starch which has been modified by

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chemical means (derivatized by octenylsuccinic anhydride to introduce hydrophobicity) and modified by use of β -amylase. Also disclosed is the high level of oxygen resistance (col. 7, l. 23).

The substitution of the starch disclosed in US 5,935,826 for the starch in the composition disclosed in US 6,723,358 would have been obvious because US 6,723,358 specifically suggests the incorporation of hydrophobically modified starches, such as those taught by US 5,935,826.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicants argue that US 6,723,358 uses a starch which is substantially ungelatinized (insoluble). This is not a persuasive argument because the reference specifically teaches that up to 30% of the starch in the matrix may be gelatinized (col. 7, l. 27), and the composition claims are open to further additions. Applicants argue that the function of the proteins in US 6,723,358 is to enhance the water binding characteristics, preventing the release of the encapsulant from the matrix which is different from the instant function. Please note that the claims under examination are composition claims, compositions have components and function is an inherent consequence of the components. As long as the reference fulfills the limitations of claimed composition, i.e. has the same components, the composition of the reference and the claimed composition are reasonably assumed to have the same effect or function.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a long horizontal stroke extending to the right.

Sandra Saucier
Primary Examiner
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April 20, 2006